REMARKS

Claims 1-9, 16-18, 28-31, 35-37, 39-47, and 54 are pending.

Claims 55-91 have been withdrawn. These claims were added in Applicants' Reply filed 10/13/05 and claim the same, or substantially the same, subject matter as the claims of Venkatraman et al., U.S.S.N. 10/850,865, entitled "Transdermal Administration of Fentanyl and Analogs Thereof." They were added for the purpose of provoking an interference with the aforementioned Venkatraman et al. application. They are now the subject of a currently filed divisional application.

The Examiner has also withdrawn claims 48-53 from consideration. Applicants request the Examiner to reconsider the withdrawal.

Claim 52 depends on pending claim 1 and claim 53 depends on pending claim 39. Both of these claims should be examined together with the independent claims upon which they depend.

Claims 48-53 correspond to originally filed claims 23-27 and 34. These claims were canceled in Applicants' Reply dated 12/20/04 when Applicants amended the claims to recite "consisting of" instead of "comprising." Claims 23-27 and 34 were canceled because they were inconsistent with the "consisting of" language. However, in Applicants' Reply filed 10/13/05, the claims were again amended to recite "comprising," as in the originally filed claims. Consistent with that amendment, Applicants reinstated originally filed claims 23-27 and 34 in the form of new claims 48-53. Claims 48-53, therefore, should be included with pending claims 1-9, 16-18, 28-31, 35-37, 39-47, and 54 for purposes of the present examination, and such action is requested.

Claims 1-9, 16-18, 28-31, 35-57, 39-47, and 54 stand rejected under 35 U.S.C. §112, second paragraph, on the ground that the phrase "substantially free" is indefinite. While Applicants continue to disagree with this rejection, Applicants have now amended the claims to delete this phrase. The claims now recite that the composition is "free" of undissolved fentanyl. As explained in the specification, a composition is "free" of undissolved fentanyl when a person of ordinary skill is unable to detect any undissolved fentanyl with an optical microscope under

the magnification conditions set forth in the specification. In view of the amendment and related remarks, Applicants request the Examiner to withdraw the rejection.

Claims 1-9, 16-18, 28-31, 35-57, 39-47, and 54 stand rejected under 35 U.S.C. §103 over WO '229 in view of US '849. WO '229 relates generally to transdermal drug delivery devices, and specifically illustrates devices for delivering nicotine. The Examiner concedes that WO '229 fails to describe such a device for delivering fentanyl, but cites US '849 for allegedly disclosing the equivalency between nicotine and fentanyl in the context of transdermal delivery devices. However, this is not the case.

At the outset, Applicants note that US '849 fails to provide a single working example of a transdermal delivery device for delivering fentanyl. The only mention of fentanyl is in claim 10, where it is listed along with nicotine and a wide variety of disparate drugs for possible transdermal delivery. The list includes, for example, a class of drugs called "diverse peptides." The mere inclusion of fentanyl in this list in no way demonstrates that persons of ordinary skill in the art recognized the equivalency between nicotine and fentanyl for purposes of transdermal delivery. In fact, the opposite is true. This is illustrated, for example, in Naik et al., "Transdermal drug delivery: overcoming the skin's barrier function," PSTT Vol. 3, No. 9 (2000), pp. 318-36 ("Naik"), a copy of which is included.

Applicants draw the Examiner's attention to Table 1 of Naik. Table 1 compares physicochemical and pharmacokinetic data for a number of transdermal delivery devices, including one for delivering nicotine and another for delivering fentanyl. The results are starkly different. In this regard, compare the aqueous solubility ("Saq"), permeability coefficient ("Kp"), clearance ("Cl"), therapeutic blood level, and mg/day delivered data for the fentanyl and nicotine patches. The data demonstrate that nicotine is significantly more soluble than fentanyl, and thus more easily incorporated in a matrix in relatively high amounts and delivered transdermally than fentanyl. Fentanyl and nicotine, therefore, are entirely different from the standpoint of transdermal delivery.

Given the disparities between nicotine and fentanyl, a person of ordinary skill, faced with the problem of designing a transdermal drug delivery device for holding relatively high amounts of fentanyl, would find no guidance from devices designed to deliver nicotine. The claimed

subject matter, therefore, would not have been obvious in view of WO'229 in combination with US '849, and the rejection should be withdrawn.

Please apply the Petition for Extension of Time Fee and any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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